DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 17, 2014

Propper Manufacturing Co., Inc.
Andrew Sharavara, Ph.D.
Chief Technical Officer
36-04 Skillman Avenue
Long Island City, NY 11101

Re: K141638
Trade/Device Name: Propper Insight™ Binocular Indirect Ophthalmoscope (BIO) Kits (Models 199185 and 199285)
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: II
Product Code: HLI
Dated: June 12, 2104
Received: June 19, 2014

Dear Dr. Sharavara:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Insight™ Binocular Indirect Ophthalmoscope.

Indications for Use:

Propper Insight™ Binocular Indirect Ophthalmoscope is an AC-adapter powered or rechargeable battery powered device for medical professionals containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, vitreous) and the retina of the eye

Prescription Use __X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Submitted by Propper Manufacturing Company, Inc.
Address: 36-04 Skillman Avenue,
Long Island City, New York 11101
Telephone: (800) 832-4300 or (718) 392-6650
Facsimile: (718) 482-8909
Contact Name: Andrew Sharavara

Date Submitted: June 12, 2014

Trade Name: Insight™ Binocular Indirect Ophthalmoscope
Common Name: Binocular Indirect ophthalmoscope

Product Code / Regulation: HLI (AC), HLJ (DC) / 21 C.F.R. 866.1570

Description: The Propper Insight™ Binocular Indirect Ophthalmoscope is an AC-powered or rechargeable battery-powered indirect ophthalmoscope that complies with standard ISO 10943:2012, Ophthalmic Instruments – Indirect Ophthalmoscopes.

The Propper Insight™ is a Binocular Indirect Ophthalmoscope (abbreviated - BIO), worn on the medical professional's head containing illumination and viewing optics intended to examine the media and the retina of the eye when used in conjunction with an ophthalmic lens.

The illumination part of the Propper Insight™ Binocular Indirect Ophthalmoscope consists of a LED (Light Emitting Diode) source, lenses, a selection of red-free, amber and cobalt blue filters, three sizes of light apertures, diffuser and illumination mirror. The device has opto-mechanical system for adjustment of illumination level, which is based on the relative positions of two polarizer filters.
The viewing part consists of viewing lenses, and mirrors that are adjustable to obtain views of the patient eye fundus.
The illumination part and the viewing part are combined in the metal housing (BIO Module) which is attached to the headband with the pivot bracket mechanism. The attachment mechanism allows the BIO Module to be pivoted between in-use (down) and out-of-use positions (up). The attachment mechanism also allows adjustment of the BIO Module relative to the user's eyes for the most optimal viewing path. The attachment mechanism includes a magnetic securement of the BIO Module in both in-use and out-of-use positions. Part of the magnetic securement operates an electric contact to automatically provide power to the illumination source in the in-use position.
The BIO Module and the power cable connector (AC-powered version), or the BIO Module and the rechargeable battery are attached to the adjustable headband.

Indication: Propper Insight™ Binocular Indirect Ophthalmoscope is an AC-adapter powered or rechargeable battery powered device for medical professionals containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, vitreous) and the retina of the eye.

Substantial Equivalence: The Insight™ Binocular Indirect Ophthalmoscope is similar in intended use, design and operating principles to the following device:

Predicate device	**510k number**
Heine OMEGA 500 binocular Indirect ophthalmoscope, LED version	K123316

Substantial equivalence to the predicate device was evaluated according to the FDA guidance document "guidance for Industry. Ophthalmoscope guidance (Direct and Indirect)" issued on July 8, 1998.

Propper Insight™ Binocular Indirect Ophthalmoscope is equivalent to the predicate device Heine Omega-500 Binocular Indirect Ophthalmoscope because both devices are designed for the same purpose, use similar light sources (LED), have the same indications for use, very similar operational principles and design, and the new device does not introduce new potential hazard or safety risks.